UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,425	07/03/2001	Maurice M. Molondy	034547-0106	1139

7590 01/14/2003

Stephen A. Bent
FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5109

EXAMINER
FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/897,425	Applicant(s) Maloney et al
	Examiner FOX	Group Art Unit 1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply -3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 10/23/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 1-21 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Claims 1-9 and 13-16 are being examined to the extent that they read on the elected invention, namely plant transformation methods and the resultant transformed plant cells and plants. The claims should be amended to reflect this subject matter, and any subsequently redundant claim should be cancelled.

The effective filing date of the general concept of the instantly claimed invention, namely the expression in plant cells of fusion proteins comprising a portion of a plant oil body protein (oleosin) gene and a gene encoding a heterologous protein of interest, is 22 February 1991, the filing date of the first parent application to disclose this concept. The effective filing date of the specific concept of the instantly claimed invention, namely the expression of thioredoxin or thioredoxin reductase as a fusion protein, is 3 July 2001, the filing date of the instant application, since no other parent application suggested or disclosed thioredoxin- or thioredoxin reductase-encoding genes or the expression of these proteins as fusion proteins with oleosins.

The application should be reviewed for errors. Errors appear, for example, in claim 21, where --a-- should be inserted before "*Carthamus*".

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 20-21, 24-32 and 36-44 of U.S. Patent No. 5,650,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the method for expressing heterologous polypeptides including enzymes in plant cells as a fusion protein with an oleosin as claimed in the patent to obtain the method for expressing heterologous polypeptides including the enzymes thioredoxin and thioredoxin reductase in plant cells as a fusion protein with an oleosin as claimed in the instant application.

Claims 1-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 13, 17-23 and 28-40 of copending Application No. 09/893,525. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary

skill in the art to utilize the method for expressing heterologous polypeptides including enzymes in plant cells as a fusion protein with an oil body protein including an oleosin, as claimed in the copending application, to obtain the method for expressing heterologous polypeptides including the enzymes thioredoxin and thioredoxin reductase in plant cells as a fusion protein with an oil body protein including an oleosin, as claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to chimeric genes comprising any type of thioredoxin reductase gene of any sequence and from any source, methods of their use, and plant cells and plants transformed therewith. In contrast, the specification and cited prior art only provide guidance for NADPH thioredoxin reductase genes and methods for their use. No guidance is provided for the isolation or characterization of other thioredoxin reductase enzymes such ferredoxin thioredoxin reductase, or for the isolation or characterization of any genes encoding it.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Insertion of --NADPH-- before "thioredoxin reductase", each occurrence, would obviate this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 and 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4-5, and dependents are indefinite in their recitation of "the [or said] recombinant fusion polypeptide" which lacks antecedent basis in claim 1 from which they depend. Deletion of "recombinant" in these claims would obviate this rejection.

Claim 6 is indefinite in its recitation in lines 1-2 of "the heterologous polypeptide" which lacks antecedent basis in claim 2. Replacement of this phrase with --said thioredoxin or thioredoxin reductase-- would obviate this rejection. Dependent claims are included in the rejection.

Claim 6 is indefinite in its recitation in lines 4-5 of "said [or the] DNA sequence" which lacks antecedent basis in claim 2. Replacement of "DNA" with --nucleic acid-- would obviate this rejection.

Claim 6 is indefinite in its recitation in line 5 of "the oil body protein" which lacks antecedent basis in claim 2. Replacement of "oil body protein" with --oleosin-- would obviate this rejection.

Claim 13 is indefinite in its recitation in lines 1- 2 of "chimeric nucleic acid sequence...oil body of a host cell comprising..." as it is unclear which of the preceding claim elements comprises the subsequently recited claim elements. If the nucleic acid sequence were intended to comprise the subsequently recited claim elements, then insertion of a comma after "cell" in line 2 would obviate this rejection. Dependent claims are included in the rejection.

Claim 13 is indefinite in line 5 of "second DNA sequence" which is confusing, since no first DNA sequence was recited. Replacement of "DNA" with --nucleic acid-- would obviate this rejection.

Claim 13 is indefinite in its recitation in lines 6 and 8 of "nucleic sequence" as it is unclear what is intended. If intended, insertion of --acid-- after "nucleic" would obviate this rejection.

Claim 14 is indefinite in its recitation in lines 4-5 of "the oil body protein" which lacks antecedent basis in claim 13. Replacement of "oil body protein" with --oleosin-- would obviate this rejection.

Claim 15 is indefinite in its recitation in line 3 of "collagenase chymosin" as it is unclear what is intended. If the individual enzymes were intended, insertion of a comma after "collagenase" would obviate this rejection.

Claims 1-21 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest methods for targeting heterologous peptides to plant oil bodies via plant transformation with chimeric genes encoding a fusion protein comprising an oleosin and a

heterologous peptide of interest, as stated in allowed parent application 08/366,783, now U.S. Patent 5,650,554.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 6, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638